RECORD NO.

14-3491

In The
United States Court of Appeals
For The Second Circuit

KOLEEN OTIS-WISHER,

Plaintiff – Appellant,

v.

MEDTRONIC, INC.,
MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants – Appellees,

FLETCHER ALLEN HEALTH CARE, INC.,
AKA FLETCHER ALLEN HEALTH CARE,

Defendant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

BRIEF OF APPELLANT

Carey C. Rose
AFFOLTER GANNON & ROSE
15 Brickyard Road
Essex Junction, Vermont 05676
(802) 878-2797

Counsel for Appellant

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

REGULATIONS

OTHER AUTHORITIES

I. STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

The District Court for the District of Vermont had jurisdiction over Plaintiff/Appellant Koleen Otis-Wisher's claim pursuant to 28 U.S.C. § 1322. The district court entered a ruling on Medtronic Defendants' Motion to Dismiss on June 25, 2013, dismissing all claims against the Medtronic Defendants. Docket Entries #89, A-8. Suit proceeded against the sole remaining defendant, Fletcher Allen Health Care, Inc., which action was resolved by settlement. Judgment was filed by the district court on August 19, 2014. *Id.* at #120, A-10. On September 17, 2014, Ms. Otis-Wisher filed a notice of appeal. *Id.* at #121, A-10. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

II. STATEMENT OF THE ISSUES

Whether the district court erred in holding that Ms. Otis-Wisher's claims against the Medtronic defendants are preempted.

Whether the district court erred in holding that Ms. Otis-Wisher did not fit the definition of "consumer" under the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, § 2451(a)(9), and ordered dismissal of that claim against the Medtronic defendants.

III. STATEMENT OF THE CASE AND FACTS

On February 16, 2014, Koleen Otis-Wisher amended her complaint to include claims against Medtronic, Inc. and Sofamor Danek USA, Inc. (Medtronic defendants), manufacturers of Infuse Bone Graft ("Infuse"). A-11 – A-25. The Medtronic defendants moved for dismissal on October 10, 2012 for failure to state a claim under FRCP 12(b)(6). United States District Court Judge J. Garvan Murtha granted the Motion to Dismiss on June 25, 2013, dismissing all claims against the Medtronic Defendants. *Otis-Wisher v. Fletcher Allen Health Care, Inc.*, 951 F. Supp. 2d 592, 2013 U.S. Dist. LEXIS 88813 (D. Vt. 2013), A-36 – A-50. Ms. Otis-Wisher subsequently settled her claim with the remaining defendant, Fletcher Allen Health Care, Inc., and the parties filed a limited dismissal solely as to claims against Fletcher Allen. The United States District Court entered the dismissal on August 19, 2014. *Id.* at #120, A-10.

Ms. Otis-Wisher's claims against the Medtronic defendants arose out of Ms. Otis-Wisher's treatment at Fletcher Allen Health Care ("FAHC") by surgeon Dr. John Braun. On March 28, 2008, Dr. Braun performed a posterior C1-C2 fusion which he augmented with a dose of Infuse, a recombinant bone morphogenetic protein ("BMP") that stimulates bone growth.

The FDA approved Infuse in 2002 for single-level anterior lumbar interbody fusions (ALIF). Infuse has been approved for lumbar fusions, not for procedures

in the cervical spine. Medtronic initially wanted to obtain approval for other uses, but clinical trials had to be halted due to patients' development of unwanted, or heterotopic, bone growth and other serious side effects.

Medtronic effectively circumvented the FDA process by having Infuse approved for a very limited purpose and then engaging in promotional activity to encourage physicians to use it in ways not approved by the FDA. The company did so by providing financial inducements to physicians to promote Infuse for off-label procedures.

Medtronic knew that the off-label use of Infuse had not been shown to be effective, could result in migration of bone growth onto nerve roots, and could increase the risk of severe complications. Medtronic never warned about these risks and instead falsely touted and actively promoted the off-label use of Infuse as safe and effective.

The use of Infuse caused devastating complications for Ms. Otis-Wisher, including: excessive bone growth in her cervical spine leading to kyphosis; pain; spasms; and difficulty swallowing and speaking. Dr. Braun's decision to use Infuse was guided by his financial relationship with Medtronic and not by an unbiased cost benefit evaluation of the risks and benefits of use of Infuse in Ms. Otis-Wisher's cervical spine. Dr. Braun had a financial agreement with Medtronic that called upon him to personally use Medtronic's products and to endorse and

promote their uses by others. Dr. Braun testified in deposition that he has had a longstanding relationship with Medtronic, which has paid him (and companies that he owns) millions of dollars. Dr. Braun's relationship with Medtronic subsequently soured and he filed a federal lawsuit against the company wherein he alleges that Medtronic used his position as a surgeon and associate professor to promote the use and sale of millions of dollars of Medtronic products. In his Complaint, Dr. Braun asserted that he is entitled to be compensated because, as part of his agreement with Medtronic, he personally used their products and influenced others to use them, significantly adding to the company's market share.

IV. SUMMARY OF ARGUMENT

The primary issue presented in this appeal is whether federal law preempts a claim against Medtronic where the company circumvented the FDA approval process by promoting the off-label use of a medical device in a way it knew was potentially harmful to patients. Medtronic argues it is entitled to complete immunity. In rejecting a similar claim, the Seventh Circuit Court of Appeals stated: "The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive." *Bausch v. Stryker Corp*., 630 F.3d 546, 549 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (U.S. 2011). The *Bausch* court observed that manufacturers who violate federal law cannot hide behind the shield of immunity

and are liable under state tort law. There exists an actionable claim against the Medtronic defendants because Koleen Otis-Wisher was a consumer dealing directly with her doctor who, given his contractual and financial relationship with Medtronic defendants, served as their agent.

V. STANDARD OF REVIEW

The applicable standard of review is *de novo* review as applied to the allegations of the amended complaint accepted as true in light most favorable to Ms. Otis-Wisher.

VI. ARGUMENT

A. MS. OTIS-WISHER'S CLAIMS ARE NOT PREEMPTED BY FEDERAL LAW

Medtronic essentially argues that it is immune from liability on the ground that all of Ms. Otis-Wisher's causes of action are preempted by federal law. In seeking blanket immunity, Medtronic makes the following two arguments: First, relying on the Supreme Court's ruling in *Riegel v. Medtronic*, 552 U.S. 312 (2008), Medtronic contends that, because it obtained FDA approval for the use of Infuse for one indication, it is entitled to preemption/immunity even though it marketed Infuse for indications the FDA had not approved. Medtronic's argument is flawed. *Riegel* and its progeny held that, while manufacturers who comply with federal law are entitled to preemption, those who violate federal law are not. *Riegel*, 552 U.S.

at 330 (state tort claims premised on violations of FDA regulations are not preempted because such claims "parallel" federal requirements); *Bausch*, 630 F.3d at 552 ("state law claims based on violations of federal law are not expressly preempted").

Second, Medtronic alternatively contends that any attempt by Ms. Otis-Wisher to allege that Medtronic violated federal law (i.e., through its impermissible off-label promotion) is preempted by the 2001 Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In essence, Medtronic argues that the "parallel claims" exception the *Riegel* Court carved out is itself preempted by a previous Supreme Court decision. Medtronic fails to explain why the Supreme Court in *Riegel* would go through the trouble of creating an illusory exception. Courts have rejected such arguments. *Bausch*, 630 F.3d at 557 (*Buckman* did not preempt plaintiffs' state law tort claims against device manufacturer that failed to comply with FDA regulations). Indeed, even the case on which Medtronic relied below rejected such a proposition. *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 784 (D. Minn. 2009) (neither *Riegel* nor *Buckman* preempt a properly pled claim that device manufacturer engaged in illegal off-label promotion and failed to provide adequate warnings regarding the off-label use it was promoting).

The Supreme Court has consistently held there is a strong presumption against preemption, especially in fields (e.g., products liability litigation) traditionally occupied by States.[1] Medtronic has failed to overcome this presumption and has failed to establish that, in passing the Medical Device Amendments to the Food, Drug and Cosmetic Act ("FDCA"), Congress envisioned it prohibiting injured plaintiffs from seeking tort recovery when harmed by a manufacturer's violation of FDCA and FDA regulations. Furthermore, the Supreme Court, through its decisions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Riegel*, has confirmed that state law tort claims arising out of a device manufacturer's violations of FDCA and FDA regulations are not preempted.

[1] See *Wyeth v. Levine*, 555 U.S. 555 (2009), where the Supreme Court ruled that a failure-to-warn claim under Vermont tort law was not preempted by federal law. Initially it should be noted that *Wyeth* is a drug case whereas the instant action deals with a device and therefore is subject to a different regulatory scheme. Nevertheless, the *Wyeth* opinion is important because it reflects the Court's strong presumption against preemption. The Court in *Wyeth* held that the pharmaceutical manufacturer defendant could have added to its packaging a stronger warning about the risks of the drug. There was no preemption, the Court explained, because federal regulations left room for the manufacturer to alter its warnings and because Congress did not specify any intent to preempt state failure-to-warn claims.

1. The FDCA and FDA Regulations Prohibit Medical Device Manufacturers From Promoting Their Devices for Unapproved/Off-Label Uses

When the FDA approves a medical device, the agency approves the product for the specific use set out in the product's approved labeling. A use approved by the FDA is referred to as an "approved" or "labeled" use. A use that does not appear in the labeling is not approved as safe and effective and is known as an "unapproved," "off-label" or "new use." The FDCA generally prohibits medical device companies from promoting their devices for off-label uses. A medical device promoted for off-label uses is deemed misbranded in violation of 21 U.S.C. § 352(f) (misbranding) and distribution is prohibited pursuant to 21 U.S.C. § 331(a) and (k). See 65 Fed. Reg. 14286 (Mar. 16, 2000); *United States v. Caputo*, 288 F. Supp. 2d 912, 920 (N.D. Ill. 2003) ("the FDCA and the corresponding FDA regulations prohibit manufacturer promotion of off-label uses."); *Riley*, 625 F. Supp. 2d at 784, n.8.

Once the FDA has approved a medical device (such as Infuse) through the premarket approval application ("PMA") process, the manufacturer/applicant is required to comply with the standards in the PMA approval order. "A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. Any changes the manufacturer

believes could affect the safety or effectiveness of the device, including any intention to promote the device for new uses, must be submitted, via a "PMA supplement," to the FDA for approval. "After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA....While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: (1) New indications for use of the device…" 21 C.F.R. § 814.39(a); see also *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 110 (2d Cir. 2006), *aff'd*, 552 U.S. 312 (2008).

While Medtronic's Infuse device was approved for use in anterior lumbar procedures, it never received approval for cervical procedures. Thus, cervical use is considered a "new indication" for which Medtronic was obligated to obtain FDA approval if it sought to promote such use. 21 C.F.R. § 814.39(a). Medtronic never obtained approval for cervical use. As such, the FDA only approved Infuse for anterior lumbar procedures and specifically asked Medtronic to take measures to prohibit the off-label use and off-label promotion of uses. Medtronic did just the opposite and began a stealth campaign to promote off-label uses.

If Medtronic wanted to legally promote Infuse for off-label cervical uses, it was obligated to obtain FDA approval for posterior uses. 21 C.F.R. § 814.39(a). Having failed to obtain said approval, Medtronic's promotion of Infuse for such off-label uses was in violation of state and federal laws, thus, it is not entitled to the preemption defense.

Medtronic's counsel argued below that following the Second Circuit's opinion in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), no legal restriction to off-label promotion is permissible. Although it is true that a divided panel of the Second Circuit voted (2-1) to disallow the criminal prosecution of an individual for making truthful representations as to the off-label use of a medical product, that ruling has no application in this case. First, *Caronia* was a criminal prosecution rather than a civil case. The concerns expressed by the majority for Constitutional safeguards do not find the same weight in this case where criminal penalties are not at stake. Moreover, the *Caronia* majority's opinion was strictly limited to its facts and does not pertain to circumstances, such as here, where the defendant misrepresented the safety and utility of a product it knew to be dangerous. A defendant making such "untruthful" statements enjoys no First Amendment protection and the laws restricting off-label promotion remain intact.

The *Caronia* panel's decision vacated and remanded the federal conviction of Jazz Pharmaceuticals' sales representative, Alfred Caronia, for conspiracy to

introduce a misbranded drug into interstate commerce, a violation of the federal Food, Drug and Cosmetic Act ("FDCA"). The FDCA makes it a criminal offense to introduce "into interstate commerce . . . any drug . . . that is . . . misbranded." 21 U.S.C. § 331(a) (general prohibition against the misbranding of drugs and devices). An FDA approved product is misbranded if its labeling fails to bear "adequate directions for use," 21 U.S.C. § 352(f), meaning directions under which a drug can be used "safely" for the purposes for which it is "intended". 21 C.F.R. § 201.5 (drugs); 21 C.F.R. § 801.5 (medical devices). The majority in *Coronia* wrote that these provisions, taken together, were construed by the government "to prohibit promotional speech as misbranding." *Id.* at 151.

The *Caronia* panel's reasoning relied on the Supreme Court's decision in *IMS Health v. Sorrell*, 131 S. Ct. 2653 (2011), which held unconstitutional on First Amendment grounds, a Vermont regulation prohibiting pharmaceutical companies from using prescriber-identifying information for marketing purposes. Although the defendant in *Caronia* sought to have the FDCA's prohibition of off-label marketing broadly declared unconstitutional, the Court invoked constitutional avoidance and instead construed the FDCA narrowly to avoid the constitutional issues that the panel majority acknowledged would be raised by the near-to-total ban on off-label marketing.

Throughout *Coronia*, the majority was at pains to emphasize that its analysis pertained to the constitutional ramification of prohibiting "truthful" statements about existing products. Invoking *Sorrell*, the panel found that the limitations of off-label promotional statements, content-based and speaker-based, were "speech" and any limitations were subject to heightened scrutiny. In ruling that the construction of the FDCA urged by the government against the defendant could not pass such heightened scrutiny, the *Caronia* panel specifically noted that the representational off-label statements were lawful because they were neither false nor misleading.

It is Ms. Otis-Wisher's contention that representations by Medtronic and its agents (including here, Dr. Braun) were not truthful as to the Infuse product, but were false and misleading. The company represented its product as safe and effective for use in the cervical spine, knowing that it was not. This conduct, Ms. Otis-Wisher submits, violated 21 U.S.C. § 352(f) (misbranding). A helpful opinion regarding the interplay between off-label promotion and preemption is *Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 402 (App. Div. 2010) ("A claim that promotion of off-label use beyond the safe harbor was coupled with a failure to warn would not be preempted."), *aff'd*, 211 N.J. 362 (2010). The Defendant was the manufacturer of a stent that had been implanted for on-label purposes but was also being implanted for an off-label use. The court noted that plaintiffs' failure to

warn claims would not be pre-empted where they could be proven by evidence independent from evidence of fraud during FDA pre-approval. In addition, it deemed defendants' failure to carry out their duty to warn the public and medical community about adverse effects associated with off-label use of the device was not a part of the PMA process and not pre-empted. The court in *Cornett* also concluded that a breach of warranty claim would survive against the manufacturer where it made voluntary statements regarding the effectiveness of the device for on or off-label uses that were not approved or mandated by the FDA.

2. There is a Strong Presumption Against Preemption

There is a "basic presumption against preemption" because preemption upsets the balance of power between the federal government and the states as independent sovereigns. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005); see also *Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008). The presumption applies in tort cases such as this because, historically, the States have possessed broad powers to protect the "lives, limbs, health, comfort and quiet of all persons." *Slaughter House Cases*, 16 Wall 36, 62 (1873); *Lohr*, 518 U.S. at 485 (applying presumption against preemption in case against Medtronic).

The presumption against preemption equally applies to federal statutes, including the Medical Device Amendments, which contain an express preemption clause. *Id.*; see also *Altria Group*, 555 U.S. at 77 ("[w]hen addressing questions of

express or implied preemption, we begin our analysis with the assumption that the historic police powers of the States are not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.").

3. Under Established Supreme Court Authority, As Espoused in *Lohr* and *Riegel*, Plaintiff's "Parallel Claims" Arising Out of Medtronic's Illegal Off-Label Promotion Are Not Preempted By Federal Law

The Medical Device Amendments of 1976 to the FDCA include an express, but limited, preemption provision for claims against manufacturers of Class III medical devices:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has twice addressed the limited scope of this preemption provision. First, in 1996, the Court held that lawsuits brought under state law against medical device manufacturers who submit "premarket notification" to the FDA are not preempted by 21 U.S.C. § 360k(a) when liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable care in the device's design, manufacture,

assembly, and sale. *Lohr*, 518 U.S. at 481, 494-95. Second, in 2008, the Court held that lawsuits brought under state law against medical device manufacturers who obtain the full federal "premarket approval" are preempted by section 360k(a) when liability is premised on violations of state law requirements that are in addition to, or different from, federal requirements regulating the devices. *Riegel*, 552 U.S. at 330. Neither case held that state lawsuits premised on violations of federal law are preempted under section 360k(a). In fact, *Lohr* and *Riegel* expressly left the door open for state law claims based on violations of federal law.

In *Lohr*, the Court rejected a preemption defense as applied to a medical device where the plaintiff based her claims on allegations the manufacturer violated federal regulations:

> [I]t is clear that [plaintiffs'] allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. At least these claims, they suggest, can be maintained without being pre-empted by § 360k, and we agree. Nothing in § 360k denies a state the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the

> additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Lohr, 518 U.S. at 495. The pacemaker leads at issue in *Lohr* had not been approved through the FDA's premarket approval process. Instead, the FDA confirmed that the leads were "substantially equivalent" to a device that was already on the market through what is known as a "premarket notification" or "§ 510(k) process." *Id.* at 478-80. The section 510(k) process is less rigorous than the pre-market approval process, so much so that *Lohr* held that such generally applicable standards are not "requirements" sufficient even to trigger preemption under section 360k(a). *Id.* at 492-93. The Court went on to explain that section 360k(a) does not preempt state rules that merely duplicate federal requirements. *Id.* at 494-95. Thus, the above quoted language in *Lohr* discussing parallel claims also applies to products such as Infuse that have gone through the more rigorous premarket approval. See *Bausch*, 630 F.3d at 551.

Nothing in the more recent *Riegel* case calls into question the ability of a patient to sue a Class III device manufacturer under state law for violations of federal law. In fact, *Riegel* emphasized that such claims are not preempted. In *Riegel*, the plaintiffs alleged that a medical device that failed was designed, labeled, and manufactured in breach of duties imposed by state common law, and

that the defects caused the plaintiffs to suffer severe and permanent injury. *Riegel*, 552 U.S. at 320. The trial court held that section 360k preempted the plaintiffs' claims of strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the device. *Id.* at 320-21. The trial court also held that section 360k preempted the Riegels' negligent manufacturing claim, but only to the extent the claim was not premised on the theory that Medtronic had violated federal law. *Id.* at 321. But the trial court allowed the Riegels to go forward on claims that Medtronic was negligent in manufacturing by failing to comply with federal standards and had breached an express warranty. Those claims were not preempted by section 360k. The trial court later granted summary judgment on those claims, apparently on the merits, and those claims were not before the Supreme Court. *Id.* at 321.

On review, the Supreme Court held that the premarket approval process imposed federal "requirements" that triggered the preemption clause of section 360k. *Id.* at 322-23. The Court further held that the tort duties implicit in a finding of liability under the common law claims brought by the Riegels would also constitute "requirements" under section 360k. *Id.* at 323-25. Ultimately, the Court concluded that, to the extent state tort law underlying the Riegels' claims would require a manufacturer's device to be safer than the device approved by the FDA, those requirements would "disrupt[ ] the federal scheme no less than state

regulatory law to the same effect." *Id.* at 325. Thus, the Court found that the state requirements implicit in the Riegels' common law claims were different from or in addition to the federal requirements and were preempted under section 360k.

The Supreme Court took care, however, to limit its holding to claims that the device at issue "violated state tort law notwithstanding compliance with the relevant federal requirements." *Riegel*, 552 U.S. at 330. The Court gave lower courts clear instructions to allow claims to proceed when they are based on claimed violations of federal law: "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330.

Riegel and *Lohr* thus confirm that state law claims based on violations of federal law are not expressly preempted by section 360k. *Lohr*, 518 U.S. at 495 ("Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."); accord *Riegel*, 552 U.S. at 330; see also 21 C.F.R. § 808.1 ("[the Medical Device Act] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act."). Thus, under both *Riegel* and *Lohr*, Ms. Otis-Wisher's claims for a traditional damages remedy under state law are not preempted.

Medtronic was obligated to obtain FDA approval for all of the uses for which it intended to promote Infuse and once Medtronic chose to intentionally promote Infuse for off-label/unapproved uses, it violated both state and federal law. 65 Fed. Reg. 14286 (Mar. 16, 2000) ("a medical device that is distributed for a 'new use' is 'adulterated'…and 'misbranded'…"); *Caputo*, 288 F. Supp. 2d at 920 ("the FDCA and the corresponding FDA regulations prohibit manufacturer promotion of off-label uses."); see also 21 U.S.C. §§ 331(a) and 352(f) (federal law prohibiting the sale and promotion of misbranded devices). Medtronic's failure to obtain approval for cervical use of Infuse, its intentional off-label promotion of Infuse, and its failure to provide adequate warnings for the off-label/unapproved uses, thus, subjects it to state law tort liability. *Riley*, 625 F. Supp. 2d at 783-84 (no preemption where plaintiff manufacturer promoted drug for off-label uses and failed to provide warnings same). As the Seventh Circuit Court of Appeals recently observed:

> Section 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law. Just as a plaintiff in an auto accident may use the other driver's speeding violation as evidence of negligence, plaintiff Bausch claims that she was injured by Stryker's violations of federal law in manufacturing the device implanted in her hip. It remains to be seen whether she can prove those allegations, including causation and damages. But if she can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants

> any requirement "different from, or in addition to, any requirement" imposed by federal law. Her claims are not preempted.

Bausch, 630 F.3d at 553.

The *Bausch* Court's finding of non-preemption in such cases is not only consistent with the Supreme Court's decisions in *Lohr* and *Riegel*, but is also in line with numerous other courts which have addressed this issue. See *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 769 (5th Cir. 2011) ("To the extent that Hughes asserts a failure to warn claim based only on Boston Scientific's failure to comply with FDA regulations, however, such a claim is not expressly preempted."); *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436 (6th Cir.2010); *Gelber v. Stryker Corp*., 788 F. Supp. 2d 145, 165 (S.D.N.Y. 2011); *Hofts v. Howmedica Osteonics Corp*., 597 F. Supp. 2d 830, 832 (S.D. Ind. 2009) (same); *Prudhel v. Endologix, Inc.*, 2009 WL 2045559 (E.D. Cal. Jul. 9, 2009) (same); *Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008) (same); *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790 (W.D. La. 2008) (same); *Riley*, 625 F. Supp. 2d at 783-84 (same); *Cornett*, 414 N.J. Super. at 402 (claims that medical device manufacturer promoted its devices for off-label uses was not preempted by *Riegel*). In sum, *Riegel* does not foreclose Plaintiff's right to seek state tort remedies for injuries caused as a result of Medtronic's illegal off-

label promotion of Infuse, but rather *Riegel* and its progeny, including *Bausch*, *Riley* and *Cornett*, confirm that such parallel claims are not preempted.

4. The Supreme Court's *Buckman* Decision Does Not Impliedly Preempt Plaintiff's "Parallel Claims" of Illegal Off-Label Promotion

Perhaps recognizing that Plaintiff has pled a viable parallel claim based upon Medtronic's off-label promotion violations, Medtronic alternatively argued that such parallel claims are impliedly preempted under the Supreme Court's ruling in *Buckman*, 531 U.S. 341 (2001). This is a most curious proposition. Namely, Medtronic argues that, to survive preemption under the 2008 *Riegel* decision, a plaintiff must show a "parallel" claim, and then in the tail end of its motion, it argues that any attempt to show a parallel claim would be preempted by the 2001 *Buckman* decision. Medtronic, thus, argues that the exception to preemption enunciated by *Riegel* in 2008 (i.e., the parallel claim exception) is itself preempted by the 2001 *Buckman* decision. Medtronic fails to explain why the *Riegel* Court would go through the trouble of creating an illusory exception. A review of the applicable authority confirms that *Buckman*, which concerned a sole "fraud on the FDA" claim, is not at all applicable to this case.

In *Buckman*, patients claimed they suffered injuries from implantation of orthopedic bone screws into their spines. The patients settled their claims against the device manufacturer and proceeded on a suit solely against a regulatory

consultant they alleged made fraudulent representations to the FDA in the course of the FDA approval process. The Supreme Court held that the FDCA as amended by the Medical Devices Amendments impliedly preempted the patients' sole cause of action for "fraud on the FDA." *Buckman*, 531 U.S. at 348. But, *Buckman* specifically distinguished such "fraud-on-the-agency" claims, i.e., claims not related to a field of law that states traditionally occupied, from claims based on state law tort principles such as in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984) and *Lohr*, 518 U.S. 470. *Buckman*, 531 U.S. at 352-53.

Ms. Otis-Wisher's claims, like those in *Lohr*, and unlike those in *Buckman*, are traditional state tort law claims, not fraud on a federal agency. Plaintiff does not complain of fraud on the FDA, rather, she claims she, herself (both directly through Medtronic's agent, Dr. Braun, and indirectly) was deceived and injured by: (a) Medtronic's actions in illegally promoting Infuse for off-label/ unapproved uses; (b) utilizing paid consultants to market the off-label use of Infuse; and (c) failing to provide adequate warning regarding the risks and dangers associated with the promoted off-label uses. Multiple courts, including courts on whose decisions Medtronic relies, have held that such claims are not preempted by *Buckman*. *Riley*, 625 F. Supp. 2d at 784 (neither *Riegel* nor *Buckman* would preempt a properly pled claim based on off-label promotion); *Cornett*, 414 N.J. Super. at 402 (claims that device manufacturer illegally promoted its device for

off-label uses and failed to provide adequate warnings would not be preempted by *Riegel* or *Buckman*); *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 899 (D. Minn. 2006) (*Buckman* did not preempt plaintiff's state tort law claims against Medtronic and further holding: "States may not be concerned about protecting federal agencies, but states have a strong interest in protecting their citizens from fraud and personal injuries"); *Bausch*, 630 F.3d at 557 (*Buckman* did not preempt plaintiffs' claims against manufacturer that failed to comply with FDA regulations); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 583, 597-98 (E.D. Pa. 2008) (*Buckman* does not preempt plaintiff's state tort law claims that pharmaceutical manufacturer failed to issue adequate warnings of risks associated with off-label uses); *Phillips v. Stryker Corp.*, 2010 WL 2270683 (E.D. Tenn. June 3, 2010) (*Buckman* did not preempt plaintiff's ability to establish a "parallel claim" as mandated by *Riegel*).

5. Medtronic Relies On Inapposite Authorities

The additional authorities cited by Medtronic are either factually distinguishable (as they do not relate to off-label promotion claims) or actually support Ms. Otis-Wisher's arguments. In *Stengel v. Medtronic Inc.*, 676 F.3d 1159 (9th Cir. 2012), a district court held that a suit against Medtronic for harm caused by one of its devices was preempted by the MDA and the FDCA and accordingly granted Defendant's motion to dismiss. A panel of the Ninth Circuit affirmed but

under a strong dissent. The Ninth Circuit subsequently granted rehearing *en banc* and has reversed and remanded. In *Stengel v. Medtronic*, 2013 U.S. App. LEXIS 621 (9th Cir. Ariz. Jan. 10, 2013), *cert. denied* June 23, 2014, the full court ruled that the MDA did not preempt a state-law claim for violating a federal-law duty under the MDA. Because the plaintiff alleged a state-law claim independent of the FDA's premarket approval process and rested on a state-law duty that paralleled a federal-law duty, the claim was not pre-empted, either expressly or impliedly, by the MDA.

Medtronic also cites to *Riley*, 625 F. Supp. 2d 769. *Riley* supports Ms. Otis-Wisher's arguments. *Riley* held that adequately pled off-label promotion claims such as Plaintiff's claims would not be preempted:

> It seems possible, though, that Riley could plead a narrow failure-to-warn claim that would escape preemption. Specifically, if Riley pleaded that (1) Cordis affirmatively promoted the off-label use of the Cypher stent in a manner that violated federal law, and (2) that, while promoting the device in violation of federal law, Cordis failed to include adequate warnings and directions about the off-label use that it was promoting, then Riley's claim might survive. Arguably, the first allegation would protect the claim from being expressly preempted by § 360k(a), because Cordis's conduct in promoting the off-label use of the stent violated federal law. And arguably the second allegation would protect the claim from being impliedly preempted under Buckman, because traditional state tort law imposes a duty to warn on a supplier of a product if it is reasonably foreseeable that an injury could result from the use of the product-and this duty includes the duty to give adequate instructions for the safe use of the

> product….Insofar as Riley sufficiently alleges that, in the course of unlawfully promoting the Cypher stent for off-label use, Cordis failed to adequately warn of foreseeable dangers of that use, Riley may succeed in asserting a claim that is neither expressly nor impliedly preempted.

Riley, 625 F. Supp. 2d at 783-84 (internal citations omitted).

Ms. Otis-Wishers's claims track the claims *Riley* found would escape preemption. Specifically, Ms. Otis-Wisher contends that Medtronic engaged in a vast campaign to illegally market Infuse for off-label uses; and in the course of this off-label promotion. Such claims are not preempted. *Riley*, 625 F. Supp. 2d at 783-84; see also *Cornett*, 414 N.J. Super. at 402 (adopting *Riley*'s reasoning and holding claims against a medical device manufacturer who promoted its device for off-label uses are not preempted).

Medtronic is now facing numerous cases around the country brought by patients injured by the off label use of Infuse. The defenses are coordinated and in each the company files the same preemption brief occurred here, either as a motion to dismiss or a motion for summary judgment. In *Cabana v. Stryker Biotech, LLC*, No. BC 465 313 (Cal., Los Angeles Co. Super. Aug. 20, 2012), a the plaintiff, April Cabana, sued Medtronic, in addition to Stryker Biotech, her doctor, and the hospital, after two different medical devices implanted during two different back surgeries resulted in debilitating and permanent injuries to her spine.

Medtronic moved for summary judgment asserting the same preemption defenses it does here. The court rejected Medtronic's arguments, holding that preemption did not apply since "plaintiff's claim is not based on allegations that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements." In contrast, Ms. Otis-Wisher is alleging that Medtronic promoted the use of its device in violation of federal requirements. Accordingly, under *Riegel*, Ms. Otis-Wisher's claims against Medtronic are not preempted. With respect to Medtronic's implied preemption arguments premised on *Buckman*, the Court held that "*Buckman* is inapposite to plaintiff's claims as plaintiff has not brought a claim for 'fraud-on-the-FDA' against Medtronic." *Id.*

B. PLAINTIFF'S COMPLAINT SET FORTH SUFFICIENTLY DETAILED FACTS

The district court determined that Plaintiff's allegations against Medtronic by and large sounded in fraud and that they had not been pled with sufficient specificity. Ms. Otis-Wisher contends that there are more than adequate statements of fact to put both Medtronic and a court on notice of the details of the conduct alleged and their impact on Plaintiff. Putting aside that the pleadings are made prior to any discovery by this Plaintiff, and the fact that Medtronic has been at pains to conceal details of its conduct, there is a copious body of information pertaining to the facts at issue. In *Dexia SA/NV v. Bear, Stearns & Co.*, 929 F.

Supp. 2d 231 (S.D.N.Y. 2013), an investor sued defendants for fraud in connection with its purchase of $1.6 billion dollars in residential mortgage-backed securities (RMBS). The investor alleged the relevant offering documents made false representations regarding the quality and selection process of the underlying loans. In support of its complaint, it cited evidence of defendants' allegedly systematic disregard of underwriting standards and due diligence practices but offered no evidence directly relevant to the RMBS at issue. Defendants moved to dismiss the complaint pursuant to Rule 9(b), arguing that the complaint failed to allege fraud with particularity because plaintiff did not plead a connection between the wrongful conduct alleged and the specific RMBS it purchased. Judge Jed S. Rakoff denied defendant's motion, holding that plaintiff's allegations in the complaint "present a picture of defendants' unsound mortgage origination and securitization practices so pervasive that a reasonable fact-finder could infer that those practices affected the securitizations at issue in this case." *Id. at* 238. As with this case, *Dexia* addressed an aggrieved party's effort to satisfy the Fed. R. Civ. P. 9(b) requirements with respect to allegations of generally improper business practices. The plaintiff asserted that reports from a due diligence vendor, Clayton Holdings, should have made the defendants aware of the allegedly widespread fraud. In *Dexia*, Judge Rakoff took the view that the plaintiff had detailed the alleged widespread business practices with particularity. Because the

scope of misconduct detailed in the complaint was asserted to be "so pervasive," the court reasoned it is reasonable to infer that the alleged practices tainted the investment at issue. Accordingly, the court in *Dexia* determined that plaintiff's general allegations of a pervasive atmosphere sufficiently connected the alleged deficiencies to the plaintiff's investment and loss. *Id*. at 238.

In the instant case, in place of a due diligence report, Medtronic has been the subject of a Congressional investigation pertaining to its promotion of "off label" Infuse use through physicians with financial ties to Medtronic. *See* Staff of the Senate Committee on Finance, *Staff Report on Medtronic's Influence on Infuse Clinical Studies*, (S. Prt. 112-38; October 24, 2012) (http://www.finance.senate.gov/library/prints/). Moreover, Medtronic was sued in a certified class action by investors who suffered financial losses as a result of the same conduct (i.e., Medtronic's illegal promotion of Infuse) at issue in this case. *Minneapolis Firefighters' Relief Ass'n v.Medtronic, Inc*., 278 F.R.D. 454 (D. Minn. Dec. 12, 2011). Medtronic settled the investor class action for $85 million. Accordingly, Ms. Otis-Wisher submits that the allegations made in the complaint are sufficient under the circumstances of this case.

C. THE VCFA IS ACTIONABLE AGAINST MEDTRONIC

The Vermont Consumer Fraud Act ("VCFA") prohibits "[u]nfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce."

9 V.S.A. § 2453(a), *et seq.* The purpose of the VCFA is to protect the public and is remedial in nature. *Fancher v. Benson*, 154 Vt. 583, 580 A.2d 51 (1990). The Act must be construed liberally to furnish a remedy and accomplish the intended purposes. *State v. Custom Pools*, 150 Vt. 533, 556 A.2d 72 (1988).

The VCFA applies to medical professionals and services. *Bridge v. Corning Life Sciences*, Inc., 997 F. Supp. 551, 552-553 (D. Vt. 1998)(upholding consumer fraud claim where conduct did not involve a matter of judgment, but questioned whether the doctor had read a pathology slide at all). Under the VCFA, the commercial and entrepreneurial aspects of professional services such as medicine are actionable. See *Kessler v. Loftus*, 994 F. Supp. 240, 242 (D. Vt. 1997). The district court ruled that the VCFA does not apply here because it is meant to protect a "consumer", defined as "any person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale ... but for ... her use or benefit...." Vt. Stat. Ann. tit. 9 § 2453(a)(9). Medtronic argued, and the court below accepted, that Ms. Otis-Wisher was not a consumer because she did not directly purchase the Infuse and that it was instead obtained and implanted by Dr. Braun. This position fails to appreciate Plaintiff's theory of the case: that there was an agency relationship between Medtronic and Dr. Braun. Any decision by Plaintiff to permit the use of Infuse in her cervical spine was based upon the conduct and representations of Dr. Braun who (by virtue of his financial

ties to Medtronic) was Medtronic's agent. The acts and statements of Dr. Braun are thus attributable to his principal. In this context, it was as if Medtronic sold the device directly to Plaintiff, placing them in the position of a seller and her into that of a consumer.

VII. CONCLUSION

Medtronic contends it was simply providing a product approved by the FDA and, thus, it should be excused and immune from all liability. Medtronic was not providing a product approved by the FDA, however, but was promoting and providing the product for non-approved, off-label uses. It could not get Infuse approved for implantation in the cervical spine because clinical studies showed the device was dangerous when used there, so they did an "end run" around the FDA. Thus, Medtronic was violating the very FDA process it now waves as a shield. This conduct injured plaintiff. Accordingly, as authorities have recognized, including *Lohr*, *Riegel*, *Bausch*, *Riley* and *Cornett*, Medtronic cannot hide behind the cloak of immunity. Although in actuality Medtronic's actions did amount to a fraud upon the FDA, this suit is not premised upon that but upon the parallel claims outlined above. Moreover, Plaintiff was aggrieved as a medical consumer by Medtronic and its agent Dr. Braun and accordingly is entitled to relief under the VCFA.

Ms. Otis-Wisher believes her Complaint is sufficient on its face to avoid preemption since it asserts viable parallel claims and accordingly She seeks reversal and remand. In the event this Court finds technical insufficiencies, however, then she would request remand for the purpose of permitting Plaintiff to amend the Complaint.

DATED at Essex Junction, Vermont this 15th day of December, 2014.

KOLEEN OTIS WISHER,
Plaintiff

By: /s/ Carey C. Rose

Affolter Gannon & Rose
Attorneys for the Plaintiff
15 Brickyard Road
Essex Junction, Vermont 05452
(802) 878-2797, Ext. 246
croseatvermontlawyers.net

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 15th day of December, 2013, I caused this Brief of Appellant and Joint Appendix to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

Scott M. Noveck
Andrew Tauber
MAYER BROWN LLP
1999 K Street, NW
Washington, DC 20006
(202) 263-3488

Counsel for Appellees

I further certify that on this 15th of December, 2014, I caused the required number of bound copies of the Brief of Appellant and Joint Appendix to be filed with the Clerk of the Court via UPS Next Day Air.

/s/ Carey C. Rose
Counsel for Appellant

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 28.1(e)(2) or 32(a)(7)(B) because:

   [X] this brief contains [*7,207*] words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), *or*

   [ ] this brief uses a monospaced typeface and contains [*state the number of*] lines of text, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because:

   [X] this brief has been prepared in a proportionally spaced typeface using [*Corel WordPerfect 12*] in [*14pt Times New Roman*]; *or*

   [ ] this brief has been prepared in a monospaced typeface using [*state name and version of word processing program*] with [*state number of characters per inch and name of type style*].

Dated: December 15, 2014

/s/ Carey C. Rose
Counsel for Appellant